IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MONTANA
GREAT FALLS DIVISION

ENVIRONMENTAL DEFENSE FUND; MONTANA ENVIRONMENTAL INFORMATION CENTER; and CITIZENS FOR CLEAN ENERGY, *Plaintiffs*, v. U.S. ENVIRONMENTAL PROTECTION AGENCY; and ANDREW R. WHEELER, in his official capacity as Administrator of the U.S. Environmental Protection Agency, *Defendants*.	Case No.: 4:21-cv-00003-BMM-JTJ The Honorable Brian Morris, Chief Judge

DECLARATION OF DR. JENNIFER MCPARTLAND

I, Dr. Jennifer McPartland, declare as follows:

1. I, Dr. Jennifer McPartland, am a Senior Scientist in the Health program at Environmental Defense Fund ("EDF"). I have held this position for over 10 years. I received my doctorate degree in microbiology in 2008 from the University of Chicago and then pursued further post-doctoral research there. The research I conducted over this period of time spanned the fields of microbiology and molecular biology. I received a Bachelor of Science in chemistry with a specialization in biochemistry from the University of Virginia in 2003.

2. At EDF, I focus on advancing science, policy, and market solutions to protect human health and the environment from harmful chemical exposures. I lead EDF's engagement in federal efforts to advance and appropriately apply new chemical testing approaches and systematic review practices in chemical hazard, exposure, and risk assessments. I also support EDF's efforts to ensure health-protective implementation of the Toxic Substances Control Act ("TSCA"), the nation's main chemical safety law, by working to build strong chemical review and risk management processes at the U.S. Environmental Protection Agency ("EPA" or "agency").

3. I currently serve on the Environmental Health Matters Initiative Committee of the National Academies of Sciences, Engineering, and Medicine, the EPA's Board of Scientific Counselors Chemical Safety for Sustainability Subcommittee, and the GreenScreen for Safer Chemicals Science Advisory Committee.

4. I am familiar with the new EPA rule "Strengthening Transparency in Pivotal Science Underlying Significant Regulatory Actions and Influential Scientific Information" published in the Federal Register on January 6, 2021, which addresses whether and how EPA may consider or rely upon studies which assess "the quantitative relationship between the amount of dose or exposure to a pollutant, contaminant, or substance and an effect" on health in setting standards or taking

other significant regulatory actions or developing "influential scientific information." *See* 86 Fed. Reg. 469, 470 (Jan. 6, 2021) ("Rule"). The Rule significantly restricts EPA's ability to consider such dose-response studies for which underlying data are not "publicly available in a manner sufficient for independent validation." 86 Fed. Reg. at 492.

5. The Rule would limit EPA's consideration of many important dose-response studies, including those that contain personal information about study participants that cannot be legally or ethically disclosed, even though such studies have been rigorously vetted using time-tested approaches that are widely accepted in the scientific community. Legal and ethical requirements and other barriers that restrict the ability to make public the data underlying these studies include requirements to shield private personal information and situations where obtaining the necessary permissions to release data is logistically difficult or impossible. Even when there are potential ways to address some of these barriers, doing so can be extremely costly and burdensome to the point of infeasibility, and/or may harm researchers' prospects for further research.

SECTION I: EDF'S USE OF STUDIES IMPACTED BY THE RULE IN OUR ADVOCACY

6. Under TSCA, EPA is required to assess potential risks from new and existing chemicals and address any unreasonable risks chemicals may pose to human health or the environment. For existing chemicals, this generally proceeds through

a three-step process. *First*, EPA designates specific chemicals as either "high priority" or "low priority." *Second*, for those chemicals designated high priority, EPA conducts risk evaluations to determine whether the chemicals pose an "unreasonable risk." As part of the risk evaluation process, EPA is required to publish a draft scope, final scope, draft risk evaluation, and final risk evaluation. *Third*, if EPA determines that a chemical poses any unreasonable risk, TSCA requires the agency to promulgate a risk management rule sufficient to eliminate the unreasonable risk. EPA allows for public comment on the chemical prioritization, assessment, and management stages of the process, and EDF actively participates in the public comment process.

7. I have long been involved in EDF's efforts to ensure that chemicals are comprehensively assessed and regulated under TSCA where warranted to protect public health using the best available science. As one recent example, EDF submitted comments on EPA's risk evaluation of trichloroethylene ("TCE"). I was directly involved in the development and writing of these comments. In our comments, EDF relied on several studies that demonstrate an association between TCE exposure and congenital heart defects, and identified such defects as the most sensitive human health effect of TCE exposure. A deep flaw in the draft and final risk evaluations of TCE was EPA's reliance on immune-related endpoints instead of congenital heart defects for its determinations of acute and chronic risks of TCE exposure. EPA's decision not to use the most sensitive endpoint for making

determinations of TCE's risks deviates from scientific best practices, defies requirements under TSCA, ignores longstanding agency policy, and is not sufficiently protective of the health of the public and vulnerable subpopulations. EDF's comments focused significantly on this fundamental flaw, highlighting studies in the scientific literature supporting identification of congenital heart defects linked to TCE exposure. If the Rule were in place, EPA would be constrained in considering EDF's comments because the data underlying a number of the dose-response studies we cited in our comments are not publicly available.

8. EPA issued a final risk evaluation for TCE on November 24, 2020[1] and is now developing a risk management rule to address unreasonable risks it identified in the risk evaluation. Under TSCA, EPA must propose the risk management rule within one year and finalize that rule within two years of the date on which it issued the final risk evaluation. EDF expects to review and comment on the proposed risk management rule. As support for our comments on the proposed risk management rule, I expect to rely on and cite a number of dose-response studies.

9. The data underlying some of the key dose-response studies we expect to reference in our comments are not publicly available for a variety of reasons.[2] I

[1] 85 Fed. Reg. 75,010 (Nov. 24, 2020).

[2] Examples of dose-response studies we plan to cite and that do not have publicly available underlying data include:

expect that making the data available through restricted access would frequently be impossible or infeasible due to logistical, financial, legal, ethical, or other constraints. As a result, EPA could choose to ignore or give less consideration to comments from EDF on the proposed risk management rule that rely on these critical studies. Restraints on EPA's ability to rely on certain dose-response studies significantly hampers the effectiveness of EDF's comments identifying the scientific flaws with EPA's current approach.

10. As another example, through a multi-step process, EPA has identified 20 additional chemicals which will undergo risk evaluations under TSCA. Each of these chemicals was designated "high priority" under procedures defined in EPA rules—procedures which involve public comment. EPA also recently took comment on draft scopes of the risk evaluations for each of these 20 substances.

11. EDF submitted comments throughout this multi-step process. In our comments on the high-priority designation of one of these 20 chemicals, formaldehyde, and on the scope of its risk evaluation, we noted that formaldehyde is

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- Paula D. Johnson et al., *Threshold of Trichloroethylene Contamination in Maternal Drinking Waters Affecting Fetal Heart Development in the Rat*, 111 Envtl. Health Persp. 289 (2003).
- Patricia T. Caldwell et al., *Gene expression profiling in the fetal cardiac tissue after folate and low-dose trichloroethylene exposure*, 88 Birth Defects Research Part A: Clinical and Molecular Teratology 111, 111–27 (2010).
- Steven P. Forand et al., *Adverse Birth Outcomes and Maternal Exposure to Trichloroethylene and Tetrachloroethylene through Soil Vapor Intrusion in New York State*, 120 Envtl. Health Persp. 616 (2012).

a known human carcinogen associated with nasopharyngeal cancer and leukemia. We relied on a number of dose-response studies in our comments on the proposed high-priority designation and on the draft scope of the risk evaluation of this chemical.[3]

12. EDF anticipates that EPA's draft risk evaluation of formaldehyde will be released in 2021.[4] EDF intends to submit comments on that draft risk evaluation that we expect will again refer to these and other dose-response studies. In assessing and commenting on the draft risk evaluation, EDF will rely on such studies to determine whether the risk evaluation sufficiently considers the body of evidence regarding potential effects of exposure to formaldehyde.

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[3] Examples of formaldehyde dose-response studies that we relied on in our comments include:

- M. Hauptmann et al., *Mortality from Solid Cancers Among Workers in Formaldehyde Industries*, 159 Am. J. Epidemiology 1117 (2004).
- Allan Hildesheim et al., *Occupational Exposure to Wood, Formaldehyde, and Solvents and Risk of Nasopharyngeal Carcinoma*, 10 Cancer Epidemiology, Biomarkers & Prevention 1145 (2001).
- Thomas L. Vaughan et al., *Occupational Exposure to Formaldehyde and Wood Dust and Nasopharyngeal Carcinoma*, 57 Occupational & Envtl. Med. 376 (2000).
- Sheila West et al., *Non-viral Risk Factors for Nasopharyngeal Carcinoma in the Philippines: Results from a Case-Control Study*, 55 Int'l J. Cancer 722 (1993).

[4] EPA identified these chemicals as high priority in December 2019, and its final risk evaluations are due 3 years after that (December 2022), subject to a six-month extension. EPA must publish draft risk evaluations for public comment and peer review with adequate time to permit the agency to meet the three-year statutory deadline.

13. The effectiveness of EDF's reliance on and presentation of these studies in our comments to EPA would be adversely impacted by the Rule because data underlying many if not most of these studies are not publicly available, and I do not expect that all the associated the data would be available via restricted access.

14. EDF also commented on the draft scopes for six phthalates that are among the 20 high-priority chemicals currently undergoing risk evaluation. We expect to comment on further EPA actions, including the draft risk evaluations EPA issues for these substances. In our comments on the draft scopes for the phthalates, we noted the links between exposure to certain phthalates and adverse health effects. In research we conducted on these chemicals, we have located dose-response studies that identify adverse health impacts.[5]

15. I anticipate that we will rely on these studies to comment on EPA's draft risk evaluation once it is released (likely in 2021). However, the effectiveness of our comments that rely on these studies will be limited by the Rule because the underlying data is not publicly available for some of them.

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[5] Examples of phthalate dose-response studies include:

- Robin M. Whyatt et al., *Asthma in Inner-City Children at 5–11 Years of Age and Prenatal Exposure to Phthalates: The Columbia Center for Children's Environmental Health Cohort*, 122 Envtl. Health Persp. 1141 (2014).
- Pam Factor-Litvak et al., *Persistent Associations between Maternal Prenatal Exposure to Phthalates on Child IQ at Age 7 Years*, PLOS ONE 9(12) (2014).

16. In each of the circumstances described above, the Rule will impede EDF's and my ability to provide influential and effective comments to EPA on various documents published by EPA under TSCA (*e.g.*, draft scopes, draft risk evaluations, proposed risk management rules) because the Rule restricts EPA's ability to consider our comments that rely on dose-response studies whose underlying data are not publicly available. This will limit our ability to provide the most compelling, scientifically informed, and accurate information to the agency, as well as our ability to advocate effectively for public health protections. For example, if comments we submit to EPA are ignored or given less weight because the data underlying studies we rely on in those comments are not publicly available or available via restricted access, we would be prevented from making the most compelling argument that science has established a relationship between formaldehyde exposure and adverse effects including leukemia.

SECTION II: BURDENS OF COMPLYING WITH THE RULE

17. Based on my understanding of the Rule, EPA will be limited in its ability to fully consider nearly any dose-response study for which the underlying data are not publicly available (or available via restricted access), which, in turn, stymies advocates, including EDF and myself, from effectively utilizing that type of scientific information in our advocacy before the agency. In the realm of public health, which EPA is charged with protecting, dose-response studies provide critical scientific

information to inform the development of chemical assessments, regulations, and other types of documents and actions EPA is statutorily required to develop and undertake.

18. The Rule will increase the burden on scientists, including myself, who rely on scientific studies to advocate and comment on EPA actions, processes, and assessments. In order to be confident that our comments can serve their intended purpose of informing EPA activities and decision-making, we will have to ensure that studies we rely on in our advocacy comply with the Rule.

19. This effort will be enormously burdensome. For a given TSCA comment, the studies that I reference may number in the hundreds. It already takes me a substantial amount of time to identify such studies and use them to prepare such a comment. To ensure that that work can serve its intended purpose—to actually be fully considered by EPA—I will need to assess every relevant study upon which we might rely to determine whether it uses data that are or could be made publicly available by the study's author(s). This will require me to engage in a complicated and involved process, including: determining what studies the Rule applies to; for those studies to which it does apply, researching whether the data are publicly available; when I cannot find the data in a publicly accessible platform, contacting and asking the study authors if the data are publicly available or could be made publicly available or available through restricted access; and, if not—even

assuming that the author or data owner is able or willing to engage with me—discussing with authors about the release of the data (including examining legal, ethical, and logistical constraints, the need to obtain consent from all study participants—which may be prohibitive—the logistics and expense of releasing the data, and more). Alternatively, I would need to devote considerable effort building a case as to why EPA should consider the studies even if the underlying data are not public. Because the Rule appears to require a study-by-study assessment, that effort would require substantial work for each study we intend to include in our comments. This will not only be unnecessarily labor intensive, but because of time and resource constraints I face in this work, I may well not be able to identify and include all relevant studies—which may well mean that I do not include some studies that are the best available science on a particular topic.

20. I will face these challenges immediately, such as with respect to comments I anticipate preparing on forthcoming TSCA draft risk evaluations and proposed risk management rules.

21. Moreover, I understand that the Rule has allowances for studies to be given lesser weight if their underlying data are not publicly available (or available via restricted access). Not only is this approach scientifically inappropriate—as the value, importance, rigor, or relevance of studies does not hinge on whether all of the underlying data are publicly available—but it will do little to reduce the burden the

Rule imposes on advocates and scientists like me. Because we will be unsure as to the weight EPA will give to a particular study, we will still need to evaluate the availability of underlying data in order to improve the prospects that the studies we include will receive at least some weight.

22. Although EPA has suggested that not *all* studies provided in a given assessment or process would necessarily be treated as "pivotal science," it has not sufficiently defined the parameters it will use to determine which studies qualify as pivotal science to reduce the burden I anticipate. If the Rule may (or may not) limit the ability of the agency to consider any and all studies which may inform a particular "significant regulatory action" or piece of "influential scientific information," advocates and scientists, including me, will still have to investigate each study upon which we rely to determine if it would meet the Rule's requirements. For example, I could submit or rely upon dose-response studies in commenting on a draft risk evaluation under TSCA (which is influential scientific information) under the impression that they would not be impacted by the Rule, only to have our comments and arguments given less weight if the agency decides that the studies are, in fact, "pivotal science." Or, conversely, to try to mitigate the risk that our comment could be given less weight, I could expend serious resources investigating the studies upon which I would like to rely (or be concerned that EPA will give less weight to certain

studies if they do not meet the Rule's requirements)—only to learn that they are not impacted by the Rule.

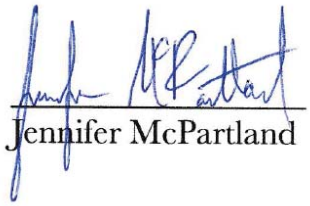
CONCLUSION

23. I am certain that the Rule will negatively affect my ability to effectively advocate for stronger public health protections under TSCA. The Rule will limit my ability to have any confidence that EPA will give any or sufficient weight to comments in which I rely on some of the best (or only) available science to demonstrate an association between a chemical and certain health impacts if the underlying data are not or cannot be made publicly available, due to legal, ethical, logistical or other constraints. In addition, the Rule will impose substantial burdens on me and my colleagues who use peer-reviewed science to advocate for public health protections if we do wish to use certain studies in our comments and other advocacy to the agency. We will have to investigate whether the data underlying each such study are publicly available; if they are not (which I anticipate will be the case for many or most studies), we will have to attempt to convince study authors to make the data available in a manner that satisfies the Rule. Even if the author or data owner agrees to try to do so, there may very well be substantial legal, ethical, logistical, and other barriers. Engaging in any of the foregoing processes will consume considerably more time and resources than previously were required. In

this manner, the Rule will substantially harm my and EDF's ability to effectively advocate for public health protections in a scientifically rigorous manner.

I declare under the penalty of perjury that the foregoing is true and correct to the best of my knowledge and belief.

Dated: January 10, 2021



Jennifer McPartland